Pathologists as Integral Care Team Members

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Diagnostic Error Definition

"[T]he failure to (1) establish an accurate and timely explanation of the patient's health problem(s) or (2) communicate that explanation to the patient."

The Problem

- 1 in 10 diagnoses
- 1 in 20 patients each year
- ‘‘It is likely that most of us will experience at least one diagnostic error in our lifetime, sometimes with devastating consequences.’’

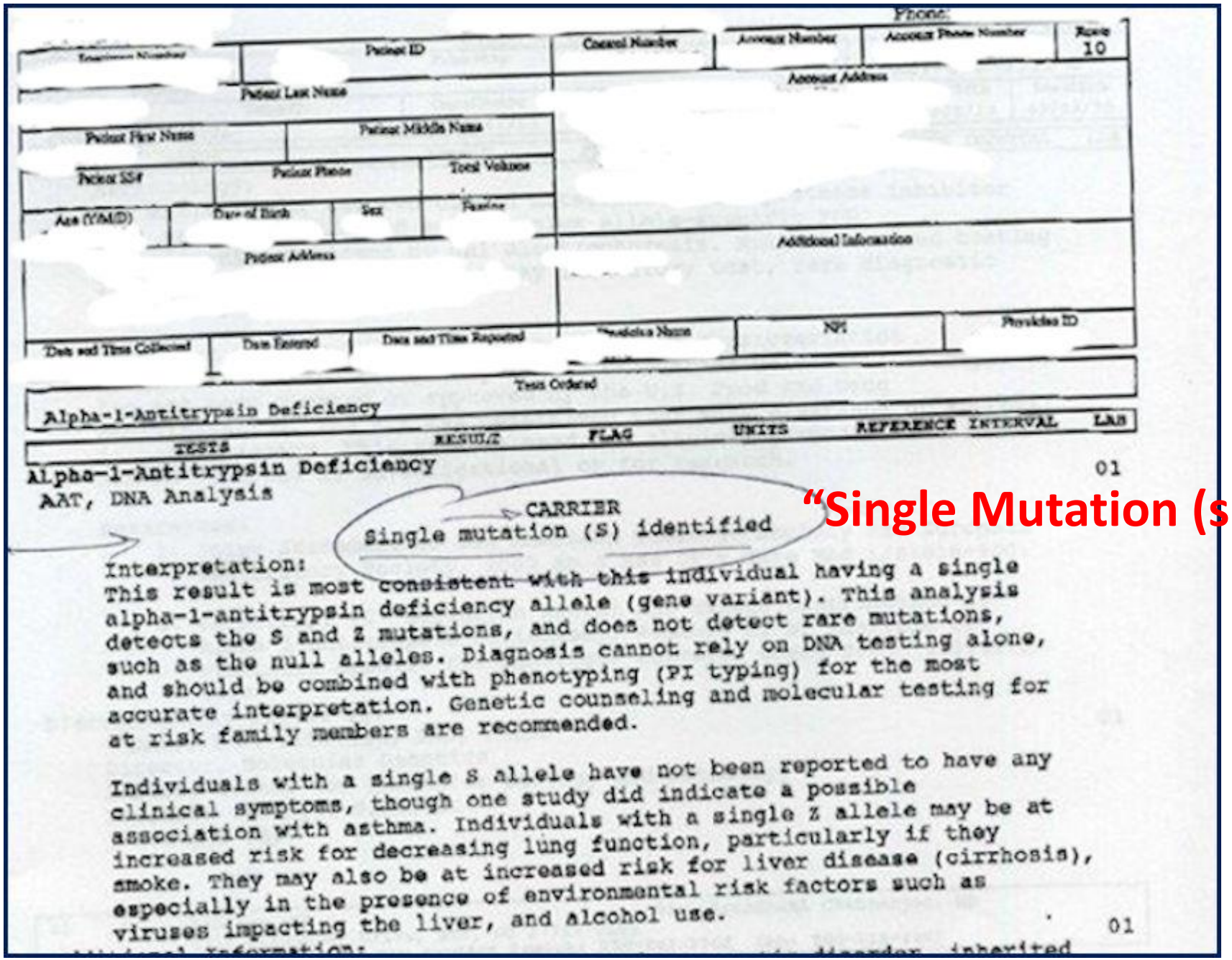
Teamwork as a Proposed Solution

GOAL 1: FACILITATE MORE EFFECTIVE TEAMWORK IN THE DIAGNOSTIC PROCESS AMONG HEALTH CARE PROFESSIONALS, PATIENTS, AND THEIR FAMILIES

- pathologists can be important contributors to team in fulfilling many of the IOM recommendations
- will focus on issues surrounding use of clinical laboratory tests

Clinical Laboratory Error Rates

- Pre-analytic 14%
  - ordering including selection
  - sample collection
  - processing
- Analytic <0.1%
- Post-analytic 7.5%
  - reporting
  - interpretation
  - communication



Phone:

Patient ID | Control Number | Account Number | Account Phone Number | Page 10

Patient Last Name | Account Address

Patient First Name | Patient Middle Name

Patient SS# | Patient Phone | Total Volume

Age (YMD) | Date of Birth | Sex | Fasting

Patient Address | Additional Information

Date and Time Collected | Date Entered | Date and Time Reported | Physician Name | NPI | Physician ID

Tests Ordered

Alpha-1-Antitrypsin Deficiency

TESTS	RESULT	FLAG	UNITS	REFERENCE INTERVAL	LAB
Alpha-1-Antitrypsin Deficiency					01
AAT, DNA Analysis					
	CARRIER Single mutation (S) identified				

Interpretation:
This result is most consistent with this individual having a single alpha-1-antitrypsin deficiency allele (gene variant). This analysis detects the S and Z mutations, and does not detect rare mutations, such as the null alleles. Diagnosis cannot rely on DNA testing alone, and should be combined with phenotyping (PI typing) for the most accurate interpretation. Genetic counseling and molecular testing for at risk family members are recommended.

Individuals with a single S allele have not been reported to have any clinical symptoms, though one study did indicate a possible association with asthma. Individuals with a single Z allele may be at increased risk for decreasing lung function, particularly if they smoke. They may also be at increased risk for liver disease (cirrhosis), especially in the presence of environmental risk factors such as viruses impacting the liver, and alcohol use. 01

Additional Information:

"Single Mutation (s) identified"

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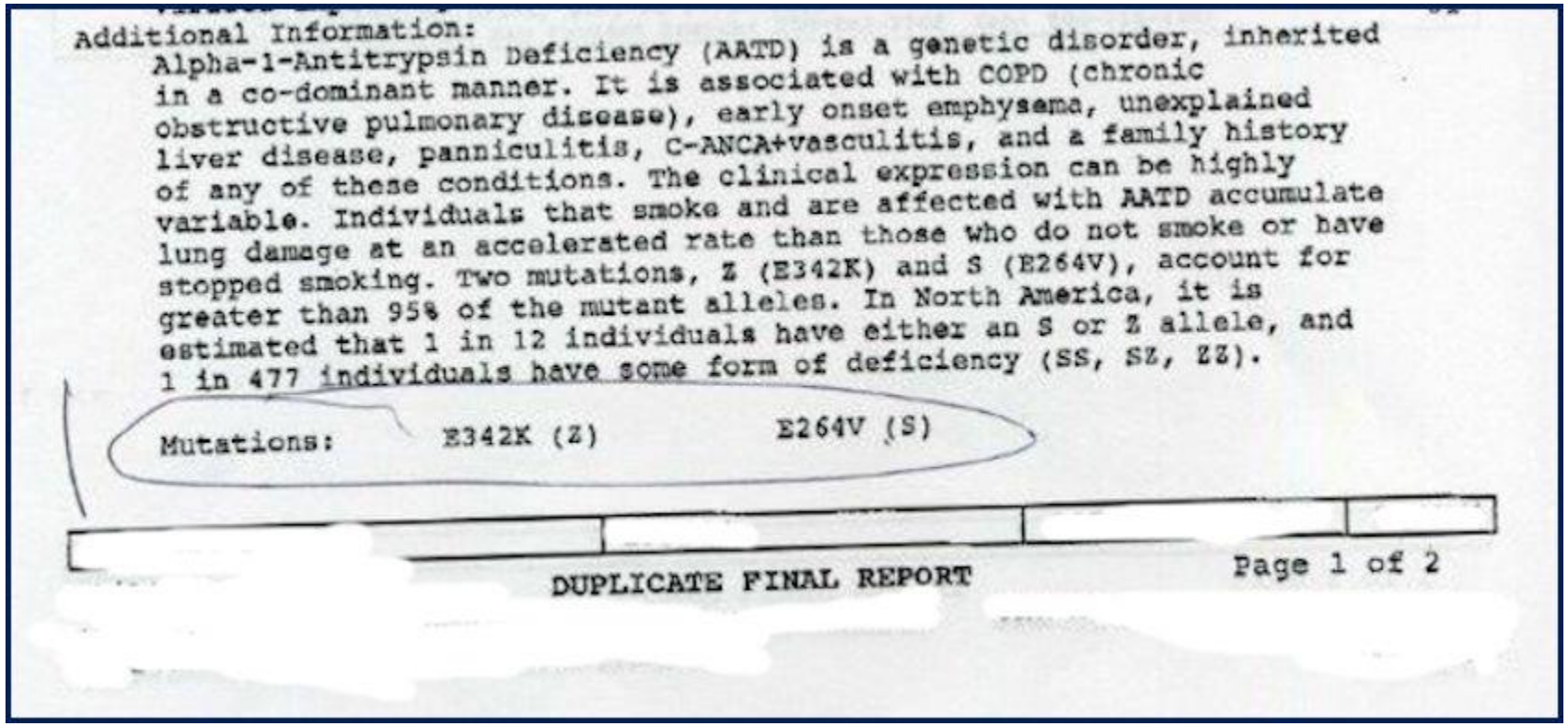

Additional Information:
Alpha-1-Antitrypsin Deficiency (AATD) is a genetic disorder, inherited in a co-dominant manner. It is associated with COPD (chronic obstructive pulmonary disease), early onset emphysema, unexplained liver disease, panniculitis, C-ANCA+vasculitis, and a family history of any of these conditions. The clinical expression can be highly variable. Individuals that smoke and are affected with AATD accumulate lung damage at an accelerated rate than those who do not smoke or have stopped smoking. Two mutations, Z (E342K) and S (E264V), account for greater than 95% of the mutant alleles. In North America, it is estimated that 1 in 12 individuals have either an S or Z allele, and 1 in 477 individuals have some form of deficiency (SS, SZ, ZZ).

Mutations: E342K (Z) E264V (S)

DUPLICATE FINAL REPORT Page 1 of 2

“Mutations: E342K (Z) E264V (S)”

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Integration of Pathologists into the Health Care Team

- Diagnostic process
  - team activity focused on the patient
- Increased complexity of laboratory test menu
  - new molecular pathology tests
  - expanded beyond knowledge of treating physicians
- Laboratory-related diagnostic errors easy to make
- Laboratory tests play a central role in patient management
  - errors in test selection or interpretation can have serious consequences
- Argues for greater role for pathologists
  - experts in test selection and interpretation

Clinical Laboratory Error Rates

- Pre-analytic 14%
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  - reporting
  - **interpretation**
  - **communication (caregivers and patients)**

Example Laboratory Consultations

- Coagulation
  - evaluation of prolonged PTT in patient without heparin
  - other potential factor deficiencies
- Genetics
  - evaluation of adult patients with cardiomyopathy or ataxia
  - evaluation of pediatric patients with developmental delay
- Molecular Oncology
  - therapeutic implications of genetic variants in tumors
- Rheumatology
  - interpretation of highly positive antinuclear antibody test
- Emergency Medicine/Cardiology
  - significance of a positive latest generation troponin test
- Therapeutic drug monitoring for pain management

Representative Evidence

Algorithmic Approach With Clinical Pathology Consultation Improves Access to Specialty Care for Patients With Systemic Lupus Erythematosus

Clinical Pathology Consultation Improves Coagulation Factor Utilization in Hospitalized Adults

Detecting familial hypercholesterolaemia in the community: Impact of a telephone call from a chemical pathologist to the requesting general practitioner

An Analysis of Clinical Consultation Activities in Clinical Pathology

Who Requests Help and Why

Algorithmic approach to testing combination with clinical pathology consultation results in more time SLE diagnosis (Chen et al. AJCP 2016)

Clinical pathology consultation improves coagulation factor utilization (Marques, et al. AJCP 2003)

Call from clinical pathologist increases rate of detection of familial hypercholesterolemia (Bell et al. Atherosclerosis 2015)

Most calls originated from primary care physicians, with requests varying by caller type (Schmidt et al. AJCP 2014)

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Consultations (Clinical Pathology)

A clinical pathology consultation is a service, including a written report, rendered by the pathologist in response to a request from a physician or qualified health care professional in relation to a test result(s) requiring additional medical interpretive judgment.

Reporting of a test result(s) without medical interpretive judgment is not considered a clinical pathology consultation.

80500 Clinical pathology consultation; limited, without review of patient's history and medical records

CPT Assistant Apr 97:9, Nov 02:9, Aug 05:9

80502 comprehensive, for a complex diagnostic problem, with review of patient's history and medical records

CPT Assistant Apr 97:9, Nov 02:9, Aug 05:9

(These codes may also be used for pharmacokinetic consultations)

(For consultations involving the examination and evaluation of the patient, see 99241-99255)

Medicare Clinical Consultation Services Requirements (42 CFR 415.130 (c))

- Must meet the following requirements:

  (1) Be requested by the beneficiary's attending physician.

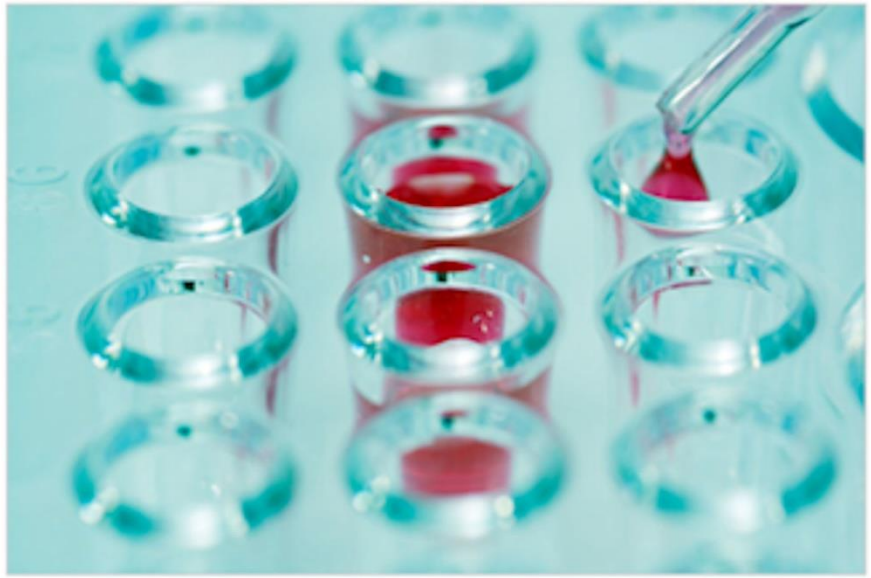
  (2) Relate to a test result that lies outside the clinically significant normal or expected range in view of the condition of the beneficiary.

  (3) Result in a written narrative report included in the beneficiary's medical record.

  (4) Require the exercise of medical judgment by the consultant physician.

Laboratories Take Aim at Proposed PAMA 2018 Medicare Rates for Tests

SEPTEMBER 27, 2017



Proposed 2018 Medicare payment rates for clinical diagnostics, calculated under the Protecting

CURRENT ISSUE

80502 RVU 1.33

80500 RVU 0.37

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IOM Recommendation 1a

- ***Goal 1: Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families***
- **Recommendation 1a: In recognition that the diagnostic process is a dynamic team-based activity, health care organizations should ensure that health care professionals have the appropriate knowledge, skills, resources, and support to engage in teamwork in the diagnostic process. To accomplish this, they should facilitate and support:**

  - Intra- and interprofessional teamwork in the diagnostic process.

  - Collaboration among pathologists, radiologists, other diagnosticians, and treating health care professionals to improve diagnostic testing processes.

IOM Recommendation 7a

- ***Goal 7: Design a payment and care delivery environment that supports the diagnostic process***
- **Recommendation 7a: As long as fee schedules remain a predominant mechanism for determining clinician payment, the Centers for Medicare & Medicaid Services (CMS) and other payers should:**
  - **Create current procedural terminology codes and provide coverage for additional evaluation and management activities not currently coded or covered, including time spent by pathologists, radiologists, and other clinicians in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients. …**

IOM Recommendation 7b

- ***Goal 7: Design a payment and care delivery environment that supports the diagnostic process***
- **Recommendation 7b: CMS and other payers should assess the impact of payment and care delivery models on the diagnostic process, the occurrence of diagnostic errors, and learning from these errors.**

Proposed CLIAC Recommendation 1

- HHS should consider requesting the American Medical Association to convene a multidisciplinary stakeholder work group to develop new and/or modify current CPT codes to adequately describe pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients.

Proposed CLIAC Recommendation 2

- HHS should consider convening a working group to study the need to revise Medicare requirements that associated with billing for clinical pathology consultations.
    - In particular, the working group should consider whether the requirement that a consult relate to an abnormal or unexpected laboratory test value limits or discourages consultations related to test ordering.
    - The working group should consider whether standing orders for consultations should be permitted in some circumstances.

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Proposed CLIAC Recommendation 3

- HHS should consider supporting one or more studies that attempt to better understand the role of clinical pathology consultation in reducing diagnostic errors, improving patient errors, and reducing health care costs
    - Such a study may involve the Center for Medicare and Medicaid Innovation and include one or more Medicare demonstration projects.